REMARKS

This is in response to the Office Action mailed on December 31, 2002 in regard to the above-identified patent application. Claims 1, 12, 17, 19, 21-42, 49-69, 71-72, 83-85, 89-91, 94-107, 225-228, 244-245, 250-255, 282, 288, 293, 297 have been amended. Claims 298-300 have been added. Claims 108-224 and 256-281 have been cancelled, without prejudice. Claims 1-107, 225-255 and 282-300 are now pending in this case. Applicants submit the newly added Claims of the present response are drawn to elected embodiments. Support for the newly added claims can be found throughout the application as originally filed.

Pursuant to Applicants' earlier election in the above-identified case, Claims 108-224 and 256-274 have been cancelled, without prejudice. Additionally, Claims 275-182 have been canceled above, without prejudice. Applicants reserve the right to pursue the subject matter of Claims 108-224 and 256-281 in a co-pending application.

35 USC §112 REJECTIONS

The Examiner has rejected Claims 1-105, 107, 226-228, 250-255, 276-278, and 288 under 35 USC §112, second paragraph. Applicants have amended Claim 12 above to remove the legend "5." Applicants have amended Claim 19 to put Claim 19 in proper dependent form. Applicants have amended Claims 21-42, 49-69, 71-72, 83-85, 89-91, 94-105, 226-228, 250-255, and 288 to include a method step.

The Examiner states that Claims 1 and 107 are substantial duplicates. Applicants respectfully disagree. Claim 1 is generally directed to the ablation of tissue within a body. Conversely, Claim 107 is generally directed to ablating tissue within an interior chamber of a patient's heart, the Claim requiring specific structure requiring such an ablation. Applicants, therefore, respectfully submit that Claim 1 and 107 are not substantial duplicates.

Since Applicants have canceled Claims 108-244 and 256-281 above, Applicants respectfully submit the rejection of any of the Claims 108-244 and 246-281 is now moot.

Applicants respectfully assert that the Examiner's rejections pursuant to 35 U.S.C. §112 have been overcome.

35 USC §102 REJECTIONS

The Examiner has rejected Claims 1-4, 9, 23, 34-39, 43-47, 55-57, 92-95, 98 and 275-280 under 35 USC 102(b) as being anticipated by U.S. Patent No. 4,445,892 (Hussein et al.), Claims 1-11, 17-19, 34-39, 48, 55-57, 92-95, 98-99, 106-107, 225-229,231 ,233, 236, and 275-180 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,725,523 (Mueller), Claims 1-4, 9-12, 17-24, 34-39, 48, 55-56, 106-107 as being anticipated by U.S. Patent No. 5,104,393 (Isner et al.), Claims 1-4, 9-11, 23-24, 34-39, 43, 55-57, 80, 82-86, 88-95, 98-99, 106-107, and 275-280 under 35 USC 102(b) as being anticipated by PCT Publication WO 96/35469 (Kesten et al.), and Claims 1-24, 40-48, 65-68, 92-95, 104-107, 225-230, 234, 236, 240-249, 275-280, 282-295 and 297 under 35 USC 102(b) as being anticipated by PCT Publication WO 98/17187 (Cox et al.). In light of the amendment and discussion made herein, it is respectfully submitted that the Examiner should withdraw these rejections.

Claims 108-224 and 256-281 have been canceled above and, thus, any rejection directed to Claims 108-224 and 256-281 is now moot.

Applicants note that the Examiner has not provided specific guidance as to what the Examiner believes to be the corresponding structures and methods in the art cited with respect to the above 35 USC 102(b) rejections.

Hussein et al. disclose a dual balloon catheter device designed to enter into a blood vessel and ablate tissue therein. The dual balloons allow for the stoppage and removal of blood flow in the area of concern so that the target tissue can be viewed and ablated. An optical fiber within a housing can then be used to transmit laser energy to ablate the target tissue. The Hussein et al. invention also allows for the passage of oxygen-bearing fluid to pass the work area and travel distal to the second balloon, allowing for a longer period of time to perform the ablation

procedure. See generally, the Abstract, Col. 4, line 37 to Col. 5, line 44 and Figures 1 and 5 of Hussein et al.

This is different than the invention of Claim 1 of the present application. Claim 1, as amended above, requires, in part, "*transluminally positioning* the ablative device ... at a first of a plurality of locations," and ablating the tissue at the first location, "*transluminally positioning* the ablative device ... at a second of a plurality of locations," and ablating the tissue at the second location, "wherein the energy delivery portion is not in fluid communication with said tissue region during the steps of ablating." (Emphasis added). The Hussein et al. reference does not disclose or suggest an ablation device which can be transluminally positioned to two of a plurality of positions, ablating tissue at each position, the energy delivery portion not in fluid communication with said tissue region during the steps of ablating. Therefore, Applicants respectfully submit the rejection of Claim 1 with respect to Hussein et al. has been overcome.

Mueller, Isner et al. and Kesten et al. each disclose distal tip ablation systems. More specifically, each disclose systems which require placement of the distal tip of the system upon target tissue. Once positioned the target tissue can be ablated. After an ablation is complete the system can be repositioned, positioning the distal tip upon another target tissue area where ablation is desired. See generally, the Abstract and front page figure of each reference. This is different that the invention of Claim 1 of the present invention. Claim 1, as amended above, requires the "positioning of the distal end portion of the tubular member adjacent to or in contact with a tissue region to be ablated" and the transluminally positioning of the ablative at a first and a second of a plurality of locations, the tissue at each location being ablated. Neither Mueller, Isner et al. nor Kesten et al. disclose or suggest such a system having a plurality of positions. Rather, Mueller, Isner et al. and Kesten et al. require the complete system to be repositioned at each ablation site. Applicants respectfully submit the rejection of Claim 1 with respect to Mueller, Isner et al. and Kesten et al. has been overcome.

Cox et al. disclose a system to ablate various lesions in the left atrium of the heart utilizing a single purse string opening and multiple cryogenic based ablating devices, each device designed

to create a specific lesion as part of a desired lesion set. The devices are placed, one at a time, upon a certain tissue surface of the heart, to create each individual lesion. The cryogenic probes are hollow structures including pathways for transport of cryogen for the ablation of the tissue. Cox et al. also discloses a cryogenic probe which can ablate epicardial tissue. See generally, the Abstract and front page figure, as well as the summary of the invention, of the publication. This is different than the invention of Claim 1. As stated above, Claim 1 has been amended to require the steps of transluminally positioning the ablative device to a first and a second of a plurality of positions, ablating target tissue at each position. There is no teaching or suggestion in Cox et al. of transluminally positioning the ablative device to a first and a second of a plurality of positions, ablating target tissue at each position, as claimed in Claim 1 of the present application.

Moreover, there is no teaching or suggestion in Cox et al. of a "flexible tubular member" within which the ablation device translates. Cox et al., as stated just above, disclose the use of a number of cryogenic probes, each probe having "an elongated shaft having an elongated ablating surface of a *predetermined shape*." (See the Abstract of Cox et al.) The predetermined shapes of the probes allow for the completion of a desired lesion set, each probe being able to ablate a lesion as part of the desired set. A flexible tubular member, as Claimed in the present invention, would eliminate the need for the multiple probe system of Cox et al.

For the reasons set forth above, Applicants respectfully submit the rejection of Claim 1 with respect to Cox et al. has been over come. Applicants further submit that no art of record, including art cited in a supplemental information disclosure statement filed herewith, teaches or suggests the invention as claimed in Claim 1. Furthermore, since Claims 2-24, 34-39, 40-48, 55-57, 65-68, 80, 82-86, 88, 89-95, 98-99, 104-105 depend for, either directly or indirectly, and further limit Claim 1, Applicants respectfully submit that these claims are also in condition for allowance.

Claim 106 has been amended above to require the "transluminally positioning of an energy delivery portion ... being adapted to direct ablative energy *substantially radially* from a longitudinal axis thereof." This is different than the systems of Mueller, Isner et al and Kesten et

al. As discussed above, these systems require distal firing elements. Neither Mueller, Isner et al. nor Kesten et al. teach or suggest using an energy delivery portion adapted to direct ablative energy substantially radially as claimed in Claim 106.

Additionally, Claim 106 was amended to require, in part, "transluminally positioning an energy delivery portion ... said energy delivery portion adapted to be positioned at one of a plurality of positions within said distal end portion of said guide catheter." There is no teaching or suggestion in Cox et al. of transluminally positioning an energy delivery portion at one of a plurality of positions.

For the reasons set forth above, Applicants respectfully submit that the rejection of Claim 106 related to Mueller, Isner et al., Kesten et al. and Cox et al. has been overcome.

Claim 107 has been amended above to require, in part, "providing a flexible tubular member having a distal end portion which is *annular* to substantially conform the distal end portion to a vasculature opening within an atrial chamber of the patient's heart." Neither Mueller, Isner et al., Kesten et al. nor Cox et al. teach or suggest a flexible tubular member having a distal end portion which is annular to substantially conform the distal end portion to a vasculature opening within an atrial chamber of a heart, as claimed in Claim 107. Applicants respectfully submit that the rejection of Claim 107 above has been overcome.

Claim 225 has been amended above to require, in part, "providing an ablation sheath comprising ... at least one lumen, a first of said at least one lumen having a *radially asymmetrical geometry* and said distal end portion comprising a contact surface parallel to a longitudinal axis thereof, said radially asymmetric geometry of said first lumen prevents rotation of said ablative device with respect to said ablation sheath during the step of advancing, whereby [ablative energy is emitted in a] predetermined direction ... toward said tissue surface." Neither Mueller nor Cox et al. teach or suggest a lumen having a radially asymmetrical geometry, preventing the rotation of the ablative device during advancement and emission of the ablative energy in a predetermined direction, as claimed in Claim 225. Applicants respectfully submit that the rejection of Claim

225 above has been overcome.

Furthermore, since Claims 226-230, 231, 233-234, 236, and 240-249 depend from, either directly or indirectly, and further limit Claim 225, Applicants respectfully submit that these claims are also in condition for allowance.

Claim 282 has been amended above to require, in part, "providing an elongated flexible tubular member having at least one lumen and a distal end portion, the distal end portion having a *plurality of ablation positions*" and "transluminally positioning the at least one ablation device ... at a *first* of the plurality of ablation positions." As stated above, Cox et al. disclose methods involving the use of a plurality of cryogenic probes, each probe has "an ablating surface of a predetermined shape" designed to create a lesion as part of a desired lesion set. (See generally, the Abstract and the first page figure). Each probe simply and indiscriminately ablates tissue where it is placed. There is no teaching or suggestion in Cox et al. of providing a *flexible* tubular member having a distal end portion having a *plurality* of ablation positions and then transluminally positioning the at least one ablation device through the lumen of the tubular member to a *first* of the plurality of ablation positions, as claimed in Claim 282. Applicants respectfully submit that the rejection of Claim 282 based on Cox et al. has been overcome.

Claims 293 and 297 have been amended in similar fashion as Claim 282, requiring, in part, "providing an elongated flexible tubular member having at least one lumen and a distal end portion, the distal end portion having a *plurality of ablation positions*" and "transluminally positioning the at least one ablation device ... at a *first* of the plurality of ablation positions." For the reasons set forth immediately above, Applicants respectfully submit that the rejection of Claims 293 and 297 have been overcome.

Since Claims 283 -292, and 294-296 depend from, either directly or indirectly, Claim 282 or Claim 293, Applicants respectfully submit that Claims 283-292 and 294-296 are in condition for allowance.

35 USC §103 REJECTIONS

The Examiner has rejected Claims 25-33, 49-54, 58-64, 69-79, 81, 86-87, 92-94, 96-97, 100-103, 225, 229, 232, 235, 238, 239, 244, 246, 250-255, 281, 293, 294 and 296 under 35 USC 103(a) as being unpatentable over Hussein et al., or Mueller, or Kesten et al., or Cox et al. The Examiner should withdraw this rejection.

Applicants note that the Examiner has rejected the above claims without combining references; that the claims are obvious in light of each reference, individually. Applicants respectively disagree. Regarding Claims 225 and 293, as set forth above there is no teaching or suggestion in Hussein et al., Mueller, Kesten et al., or Cox et al. of the methods recited in Claims 225 and 293 of the present application. Since none of the cited references teach or suggest these methods, there can be no motivation to combine such references. For example, there is no motivation in the cited art to provide an ablation sheath having a lumen having a *radially asymmetric geometry* such that an ablation device being advanced within the lumen will not rotate with respect to the ablation sheath and emit ablation energy in a predetermined direction, as claimed in Claim 225.

Additionally, there is no motivation in the cited art to provide a flexible tubular member having at least one lumen and a distal portion having a plurality of ablation positions, such that an ablation means can be transluminally positioned until the ablation means is at a first of the plurality of ablation positions where the position of the ablation means is proximate to the location on the epicardial surface to form at least part of a lesion around the pulmonary veins, as claimed in Claim 293.

For the reasons set forth above, Applicants respectfully submit that this rejection has been overcome.

Conclusion

In summary, none of the cited references, alone or in combination, disclose the inventive methods as claims in the present application. Thus, in view of the above amendments and the discussion relating thereto, it is respectfully submitted that the instant application, as amended, is

in condition for allowance. Early reconsideration and reexamination is respectfully requested.

Respectfully Submitted,

By: Ross M. Carothers
Ross M. Carothers
Agent for Applicants
Reg. No. 44,593

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AFx inc.
47929 Fremont Blvd.
Fremont, CA 94538
Phone: (510) 651-7430
Facsimile: (510) 623-4088